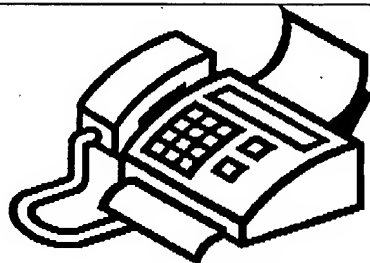


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**JUL 09 2007**



**A facsimile from**

**Paul Thompson**  
858-202-3193

**To:** Shumaya B. Ali  
Fax number: 571-273-8300

**Date:** 7/9/2007

**Regarding:** Office Action dated 4/4/07

**Comments:**

24 pages including this

JUL 09 2007

Date:07/07/07

Response to Office Action dated 04/04/07

Re: 10/634,369

Thank you for helping me straighten out some mistakes. It also made me realize I have not communicated what my invention really is. I have included some comments from users of my cannulas to help convey that this invention is a big deal with many improvements that make a difference in their lives. I also took some photos of brand X and my cannulas to show the difference. My invention is simple and very effective and the pieces have been around a long time but no one else has ever put the pieces together. If they had it would be too valuable not to have it patented. In a nutshell I will show that using soft (actually more flexible) tubing is contrary to what is known about making cannulas. And I will show that using more flexible tube for a cannula is a worthless idea without a second bit of information about the nosepiece. There isn't anything to suggest softer hose let alone anything that suggests both the more flexible hose and a certain nosepiece.

Therefore, before I address each point in the letter, I want to attempt to clarify what my invention is. It is an invention in its truest sense. It is very effective and, although the end result is simple, it required, insight, craftsmanship, perseverance and a bit of luck. This invention must be considered as a whole because the individual pieces aren't very new (except the nosepiece). Simple does not automatically mean obvious, particularly when it is completely opposite to what has been known for many years

#### **Patent and design history of the nasal cannula**

Vinyls (PVC or polyvinylchloride) were first employed to fabricate disposable medical devices during World War II. Since then, vinyl has become by far the most commonly used polymer in the medical plastics industry.

Today, millions of cannulas are manufactured per year and nearly all of them use a design that dates back to 1957. In the 50 years since there have been two more major innovations (out of at least 85 patents and applications related to cannulas) and mine is the fourth. Short story:

1. 1957, #2,931,358, D.S. Sheridan-used two small diameter oxygen tubes instead of straps to support nosepiece. Actually the ends of the tubes were pointed into the nostrils
2. 1969, #3,643,660, Hudson-invented an injection-molded nosepiece designed to align itself with the face to point the prongs so they don't blow oxygen on the sensitive nasal wall. Inexpensive to produce, these cannulas were manufactured in the hundreds of millions and are still the most widely used. The cannula with an injection molded nosepiece supported by two hoses is what I refer to when I say "modern cannula".
3. 1977, #4,106,505, Salter-introduces a dip molded nosepiece that is softer and points the oxygen prongs more accurately. The body is tall and narrow and wraps

around the upper lip like a belt. The prongs point in the tall direction so when the belt is on the lip the prongs point up. Now that the patent has run out there are plenty of imitators using dip-molding, which are considered premium cannulas. Since then, nothing new has reached the marketplace.

All three of these inventions and all known cannulas on the market today use the same tubing. It is the same material, the same hardness and the same dimensions because time has shown that is what works best for cannulas. In order for the cannula to work properly, the tubing has to be stiff in the twisting direction so that holding one end rigid will make it hard for the nosepiece at the other end to rotate, thus keeping the oxygen delivery prongs pointing upward when gravity wants them to point down. This is not widely known within the industry and various other reasons for using stiff tubing are often given, usually related to crush resistance. The idea to use soft tubing to improve comfort is a reasonably obvious idea to a person outside the industry but those within know that it doesn't work as expected because, even though the tubing is more comfortable, the cannula pointing is uncontrolled and that outweighs any improvements. Therefore, the Holy Grail of cannula design is to figure out how to use more flexible tubing without the downside and still keep the simplicity of the "tubing supported nosepiece" design of a modern cannula. I have included some photographs to better illustrate prior art and my own invention.

#### **Pictures**

Below is a picture of my cannula (left) with extra flexible tubing and a standard cannula (right) with normal stiff tubing that refuses to straighten out. In both cases the prongs point upwards correctly but they do so for completely different reasons. Another picture shows what happens when the nosepiece on the right is used with the flimsy tubing on the left. Stiff tubing (right) is harder to twist and this keeps the prongs from rolling over. Notice the nosepiece on the left has most of its weight below where the tubing attaches. This makes it bottom heavy and the prongs point up. It is clear from the picture that the tubing on the left is better behaved than the tubing on the right.

